

Amendment and Response

Page 14 of 17

Serial No.: 09/600,392

Confirmation No.: 4850

Filed: September 8, 2000

*For: AN AUTOREGULATORY SYSTEM FOR VALIDATING MICROBIAL GENES AS POSSIBLE
ANTIMICROBIAL TARGETS USING A TETRACYCLINE-CONTROLLABLE ELEMENT***Remarks**

The Office Action mailed June 17, 2003 has been received and reviewed. Claims 1, 5, 7-14, and 77 having been amended, claims 2, 4, 6 and 81 having been cancelled, and claim 82 having been added, the pending claims are claims 1, 3, 5, 7-80, and 82. Claims 21-76 having been withdrawn from examination by the Examiner, the claims currently under examination are 1, 3, 5, 7-20, 77-80, and 82. Reconsideration and withdrawal of the rejections are respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 1-20 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner asserted that the metes and bounds of the recitation "mathematically significant difference" in claim 1 are not clear, as it is unclear just how different the two groups must be in order for the difference to be considered "mathematically significant" (page 3 of Office Action mailed June 17, 2003).

Applicants continue to traverse this rejection. As previously presented, Applicants submit that the recitation "mathematically significant difference between the two groups of animals in the survival rates, levels of microbes, or levels of infection present" has a clear meaning to those of ordinary skill in art. As explained in the specification, on page 16, lines 18-20, such a difference can be "quantified with well known statistical tests" and can be "determined by one [of] ordinary skill in the art of evaluating microbial infections."

However, to expedite prosecution, Applicants have amended claim 1 to recite "wherein a difference between the two groups of animals in the survival rates, levels of microbes, or levels of infection present identifies the gene product as important to a microbe's ability to infect or sustain an infection in a mammal." Applicants submit that the metes and bounds of the claim are clear. As explained in the specification, on page 16, lines 18-20, such a difference can be "quantified with well known statistical tests" and can be "determined by one

Amendment and Response

Page 15 of 17

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[of] ordinary skill in the art of evaluating microbial infections." Withdrawal of the rejection of claims 1-20 under 35 U.S.C. §112, second paragraph, is respectfully requested.

The 35 U.S.C. §103 Rejection

The Examiner rejected claims 1-4, 6, 8-20, and 77-80 under 35 U.S.C. §103(a) as being unpatentable over Bostian et al. (WO 96/40979) in view of Setterstrom et al. (U.S. Patent No. 6,309,669 B1) and further in view of Burnham et al. (U.S. Patent No. 5,891,670) or Nesin et al. ("Cloning and Nucleotide Sequence of a Chromosomally Encoded Tetracycline Resistance Determinant, *tetA*(M), from a Pathogenic, Methicillin-Resistant Strain of *Staphylococcus aureus*," *Antimicrobial Agents and Chemotherapy*; 1990, 34:2273-2276). This rejection is respectfully traversed.

For reasons already of record, Applicants continue to submit that the Examiner has failed to establish at least two of the basic criteria of a prima facie case of obviousness. One, the Examiner has failed to establish that there is a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings of the cited references. Two, the Examiner has failed to establish that the prior art references, when combined, teach or suggest all the claim limitations.

However, to expedite prosecution, Applicants have amended claims 1 and 77 to recite "where said polynucleotide sequence encoding a tetracycline resistance protein is contained on a tetracycline resistance and repressor DNA cassette (TRRDC), said TRRDC comprising a tetracycline repressor gene and a tetracycline resistance gene; where said TCE is operably linked to a polynucleotide sequence encoding a reporter gene (RG) and a target gene (TG)." Applicants reserve the right to continue prosecution of cancelled subject matter in a continuing application.

Applicants respectfully submit that Bostian et al. in view of Setterstrom et al. and further in view of Burnham et al. or Nesin et al. do not teach or make obvious "[a] process for the identification of a microbial gene encoding a gene product that is important to a microbe's

Amendment and Response

Page 16 of 17

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ability to infect or sustain an infection in a mammal" (claims 1, 3, 5, and 7-20) or "[a] process to regulate expression of a gene product by a microbe in a mammalian host with tetracycline or a tetracycline analog" (claims 77-80 and 82) "where said polynucleotide sequence encoding a tetracycline resistance protein is contained on a tetracycline resistance and repressor DNA cassette (TRRDC), said TRRDC comprising a tetracycline repressor gene and a tetracycline resistance gene; where said TCE is operably linked to a polynucleotide sequence encoding a reporter gene (RG) and a target gene (TG)."

Applicants respectfully submit that claims 1, 3, 5, 7-20, and 77-80 are not unpatentable over Bostian et al. in view of Setterstrom et al. and further in view of Burnham et al. or Nesin et al. Withdrawal of this rejection under 35 U.S.C. §103(a) is respectfully requested.

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Page 17 of 17

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Summary

It is respectfully submitted that the pending claims 1, 3, 5, 7-20, 77-80, and 82 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Ford et al.

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PATENT TRADEMARK OFFICE

Nov. 17, 2003
Date

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17th day of **NOVEMBER**, 2003, at 9:40 am (Central Time).

By:

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